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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
FOLEY, SHANON A	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/810,501	PAUL ET AL.	
	Examiner	Art Unit	
	Shanon Foley	1648	

-- The MAILING DATE of this communication appears n the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) *1-29 and 32-38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *30,31 and 39-41* is/are rejected.

7)☒ Claim(s) *30, 39* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The examiner of your application has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1648, Examiner Foley.

In view of the appeal brief filed on September 7, 2004, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) request reinstatement of the appeal.

If reinstatement of the appeal is requested, such request must be accompanied by a supplemental appeal brief, but no new amendments, affidavits (37 CFR 1.130, 1.131 or 1.132) or other evidence are permitted. See 37 CFR 1.193(b)(2).

Claim Objections

Claims 30 and 39 are objected to because of the following informalities: the claims recite, "of from". Only one of these words is necessary. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30, 31 and 39-41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The preamble of claim 30 states that the claimed kit is for the differential diagnosis of North American and European PRRSV strains. However, the kit only comprises primers that hybridize to Iowa strains of PRRSV and component (c) specifically states that the primers amplify a North American strain and do not amplify a European strain. This recitation contradicts the preamble. In addition, it is not clear how the claimed kit will allow the differentiation of any North American PRRSV strain since the kit is only required to comprise a reagent and two primers that selectively hybridize to specific PRRSV Iowa strains. This rejection also affects claim 31.

Both of the kits claimed, recited in claims 30 and 39, are drawn to kits for assaying PRRSV with a first primer that selectively hybridizes to any portion of specific Iowa strains of PRRSV and a second primer that is required to hybridize downstream of the sequence that the first primer hybridizes to. It is unclear what the object of claimed kit assay is because if it is a priori known which portion of the specific Iowa strain the first primer hybridizes to, so that the second primer hybridizes downstream of the first primer (as required by the claims), then the identity of the PRRSV strain being amplified would already be known. This rejection also affects claims 31, 40 and 41.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 30, 31, 39 and 40 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for reasons of record.

Applicant argues that given the knowledge available in the art regarding the sequences of the Iowa and Lelystad viruses, the skilled artisan would be able to design primers without undue experimentation. However, undue experimentation is not a prerequisite for evaluating whether the instant subject matter is adequately described. Applicant is reminded that *Vas-Cath Inc. v. Mahurkar*, 19USPQ2d 1111, makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

With respect to claims 30 and 31, applicant cites Figure 17C, line 7, which shows a number of nucleotides that are deleted in the Lelystad virus as compared with Iowa strains. Applicant asserts that given this information, one of ordinary skill could amplify Iowa strains without amplifying Lelystad.

A review of the Figure has been fully considered, but is found unpersuasive. While the figure shows sequences that are not similar between Iowa and Lelystad strains, the instant primers are not limited to amplifying sections of an Iowa PRRSV genome that may be different from Lelystad. The first primer of claim 30 is required to be anywhere from 10 to 50 nucleotides in length and selectively hybridize to any portion of a genomic segment of an Iowa PRRSV. The second primer is also 10 to 50 nucleotides in length and is required to hybridize to an Iowa strain anywhere downstream of the first primer. There is no indication in the claim that the first or

second primer does not or cannot bind to a portion of an Iowa strain that is conserved in the Lelystad strain.

In response to the rejection of claims 39 and 40, applicant cites pages 88-89 and argues that the specification provides pairs of primers that can identify the Iowa and Lelystad strains and how one skilled in the art would be able to design such primers in order to identify strains. Applicant also compares the instant claims with Example 9 of the Written Description Guidelines.

Applicant's arguments have been fully considered, but are found unpersuasive. The primers claimed are required to perform a specific function. However, the structural elements necessary to perform the required function have not been described. It is not agreed that the instant disclosure provides written description for a representative number of species of primers that selectively amplify a North American PRRSV strain but not a European strain by actual reduction to practice. The disclosure only describes only the desired features of such primers but no actual primers. It is not agreed that the three pairs of primers, actually only five different primers, disclosed at page 88-89, make up a representative number of species of the genus of primers that identify both the lowa strain and the Lelystad strains, since they correspond to only a very limited portion of the viral genome. The structural requirements of the primers claimed have not been adequately described to perform the required function. A definition by function alone "does not suffice, to sufficiently describe a coding sequence "because it is only an indication of what the gene does, rather than what it is." *Eli Lily*, 119 F.3 at 1568, 43 USPQ2d at 1406. Therefore, there is no parallel between the instant claims and Example 9 of the Written Description Guidelines and the rejection is maintained for reasons of record.

Claims 30, 31, 39, 40 and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Both of the kits claimed, recited in claims 30 and 39, are for assaying PRRSV with a first primer that selectively hybridizes to any portion of specific Iowa strains of PRRSV and a second primer that is required to hybridize downstream of the sequence that the first primer hybridizes to. The first and second primers in the kit each comprise any 10 to 50 nucleotides of the specific Iowa strains recited. The kit of claim 30 is for the differential diagnosis of any North American and European PRRSV (stated in the preamble) and the kit of claim 39 assays for any PRRSV. Claim 41 is the only claim that recites specific primers encompassed by claim 39. These specific sets of primers are based on the Lelystad sequence and were able to identify specific Iowa strain VR 2385. However, the primers encompassed by the kit of claim 39 is any primer that identifies any PRRSV, not merely the Lelystad and VR 2385 strains. There is no evidence in the specification that these specific primers would enable the skilled artisan to identify any existing PRRSV besides the two strains the disclosure has shown that the primers specifically bind to.

The skilled artisan would also be unable to make the primers of each kit to meet the goal of the preamble for each of the kits because the structural elements necessary to distinguish between any North American and European strain is not taught in the specification. The primers claimed are only required to bind to specific Iowa strains. The skilled artisan would not predict that the primers would be able to amplify any PRRSV strain. Key et al. (Veterinary Microbiology. 2001; 83: 249-263) disclose the genetic variation and phylogenic analysis of the

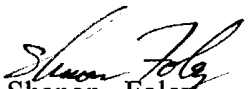
ORF of the major envelope protein of acute PRRSV. Key et al. teach that isolates from North Carolina and Iowa share 88-95% sequence identity at the nucleic acid level and these strains only shared 61-63% nucleotide sequence identity with European strains (including Lelystad), see the first paragraph of the "Results" section and Table 2. Key et al. also teach that six Iowa strain isolates are more closely related to one another that Iowa strain 98-37120-2 since the sequence similarity between the 98-37120-2 virus and the other six Iowa strains is only 88-89%, see the last paragraph bridging pages 260-261. The claimed kits comprise two primers that are 10 to 50 nucleotides in length and bind anywhere in the genome to the specific Iowa strains recited. These primers are required to differentiate between any North American and European strains as well as amplify and detect any PRRSV. Given the sequence divergence between the genotypes and various strains of PRRSV within each genotype, the skilled artisan would be unable to amplify any North American or European PRRSV. The specification does not demonstrate that any 10 to 50 nucleotide sequence within any portion of the genome of the specific Iowa strains recited is conserved among all PRRSV. Since the identity of a test virus may not be known, the skilled artisan would be unable to predict whether the first primer, designed from any 10 to 50 mer of a specific Iowa strain, would be able to hybridize to an unknown sequence. The skilled artisan would also be unable to predict how to design the second primer that is required to bind downstream of an unknown sequence from the first primer. For these reasons, it is determined that the instant claims would require an undue quantity of experimentation to make and use the invention claimed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shanon Foley whose telephone number is (571) 272-0898. The examiner can normally be reached on M-F 10:00 AM - 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Shanon Foley
Primary Examiner
Art Unit 1648